UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

EUGENE DIVISION

UNITED STATES OF AMERICA, 11-6370-TC

Plaintiff, FINDINGS AND RECOMMENDATION

v.

TRUMAN J. BERST, an individual d/b/a ALTERNATIVE HEALTH & HERBS REMEDIES,

Defendant.

COFFIN, Magistrate Judge:

Plaintiff United States of America brings this action under 21 U.S.C. § 332(a) to enjoin defendant from further distributing products that allegedly violate the Federal Food, Drug, and Cosmetic Act ("FDCA"). Specifically, plaintiff alleges that defendant is acting in violation of: 21 U.S.C. § 331(d), by distributing into interstate commerce new drugs without Federal Drug Administration ("FDA") review; and 21 U.S.C. § 331(a), by introducing misbranded drugs into interstate commerce. Before me is defendant's Motion to Dismiss (# 4) pursuant to Fed. R. Civ. P. 12(b)(6). For the reasons set forth below, I recommend that this court deny the motion.

Background

Defendant, a sole proprietor doing business as Alternative Health & Herbs Remedies, promotes and distributes numerous products that constitute new drugs. In September, 2004, FDA conducted an inspection of defendant's manufacturing facility. During that inspection, FDA determined that several products manufactured and distributed by defendant were drugs neither recognized as safe and effective nor approved by FDA. Consequently, FDA sent defendant a warning letter, dated March 17, 2005. The letter instructed defendant that continued distribution of the identified products was prohibited under 21 U.S.C. § 331(d).

In 2006, FDA reviewed defendant's website, which continued to market his products in a way that caused them to be drugs. On January 16, 2007, FDA issued a second warning letter to defendant. Both the 2005 and 2007 letters warned defendant that continued violations could result in further regulatory action, including seizure and/or injunction. In July 2011, FDA purchased ten of the products alleged to be drugs. The purchased products were shipped from Albany, Oregon to Maryland and Washington. Defendant continues distribution of the products in controversy.

Discussion

Defendant asserts four arguments in support of his Motion to Dismiss: (1) that defendant's products are not drugs; (2) that FDCA violates his Fifth and Fourteenth Amendment rights; (3) that FDCA is void for vagueness; and (4) that FDA has singled defendant out for arbitrary and discriminatory enforcement. (#4).

In considering a motion to dismiss, courts must accept all allegations of material fact in the complaint as true. Erickson v. Pardus, 551 U.S. 89, 93-94 (2007). Courts must construe the alleged facts in the light most favorable to the plaintiff. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974).

Rule 8(a) governs pleadings and requires "a short and plain statement of the claim showing that the pleader is entitled to relief...." Fed. R. Civ. P. 8(a). In Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), the Supreme Court addressed the pleading standard required under Rule 8. In evaluating the sufficiency of a pleading, the Twombly court concluded that "once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." Twombly, 550 U.S. at 563. Twombly further emphasized the need to include sufficient facts in the pleading to give proper notice of the claim and its basis. "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 555.

Two critical principles emerge from the Twombly holding. First, a skeletal recitation of the elements of a cause of action clothed in mere conclusory statements will not survive a Rule 12(b)(6) motion to dismiss. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009). Second, the well-pleaded facts of a complaint must state a plausible claim for relief. Id. at 1950.

Principally, defendant argues that his products are not drugs and as such, the sale of those products is not proscribed by FDCA. Whether true, a Rule 12(b)(6) motion is an inappropriate vehicle for an evidentiary challenge. Even, however, assuming arguendo that plaintiff's argument that his products were not drugs and not subject to regulation was cognizable in a Rule 12(b)(6) motion, his motion to dismiss would fail. Defendant does not challenge the allegation in the complaint that his products are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Thus, the court must

accept this allegation as true. I recommend that this aspect of defendant's motion be dismissed.

Next, defendant argues that FDCA violates his Fifth and Fourteenth Amendment rights to Due Process and Equal Protection. Before reaching the constitutionality of FDCA, I find that the complaint does not violate either of those rights. Thus, I recommend that this challenge to the complaint be denied, insomuch that it is asserted under Rule 12(b)(6). Yet, even if a constitutional challenge to FDCA were cognizable under Rule 12, I again find that FDCA violates neither of those rights. Particularly, I find that defendant's Fourteenth Amendment Equal Protection right is not violated because, by its own terms, the Fourteenth Amendment does not apply to defendant in this action. Nevertheless, I discuss defendant's equal protection claim under the Fifth Amendment, because it embodies the same notions of equal protection guaranteed by the Fourteenth Amendment. Weinberger v. Wiesenfeld, 420 U.S. 636, 638 (1975).

Equal Protection is a direction that all persons who are similarly situated should be treated alike. Plyer v. Doe, 457 U.S. 202, 216 (1982). Notwithstanding defendant's argument that FDCA unjustly protects the pharmaceutical industry, I find that FDCA is a statute of general applicability that does not treat persons who are similarly situated inconsistently. Indeed, like other persons similarly situated, defendant may seek approval from FDA to market his products pursuant to 21 U.S.C. § 355. Accordingly, I find that FDCA does not violate defendant's right to Equal Protection of the laws.

I similarly find that FDCA does not violate defendant's Due Process rights. The Due Process Clause protects those fundamental rights and liberties that are, "'objectively, deeply rooted in this Nation's history and tradition,' and 'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed.'" Washington v. Glucksberg, 521 U.S. 702,

721 (1997) (citations omitted). Defendant's argues that FDCA infringes upon a right to live longer. However, I find that there is no indication that FDCA violates a fundamental right protected by the Fifth Amendment. Indeed, the Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty. Gonzales v. Carhart, 127 S. Ct. 1610, 1636 (2007).

Third, defendant asserts that FDCA is void for vagueness. This claim warrants little discussion, because it fails to assert a challenge to the complaint itself. In an abundance of caution, I have reviewed the statute, and I find that it is not vague. Accordingly, I recommend that this challenge be denied.

Finally, defendant argues that plaintiff impermissibly singled him out for arbitrary and discriminatory enforcement of FDCA. Again, this argument falls outside the scope of a Rule 12(b)(6) motion, and I therefore recommend that it be denied.

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Conclusion

For the reasons set forth above, I recommend that defendant's motion to dismiss be denied. The Findings and Recommendation will be referred to a United States District Judge for review. Objections, if any, are due no later than fourteen days after the date this order is filed. The parties are advised that the failure to file objections within the specified time may waive the right to appeal the District Court's order. See Martinez v. Ylst, 951 F.2d 1153 (9th Cir. 1991). If no objections are filed, review of the Findings and Recommendation will go under advisement on that date. If objections are filed, any party may file a response within fourteen days after the date the objections are filed. Review of the Findings and Recommendation will go under advisement when the response is due or filed, whichever date is earlier.

IT IS SO ORDERED

DATED this 31 day of January, 2012.

THOMAS M. COFFIN
United States Magistrate Judge